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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,429	11/02/2005	Johanna M. Rommens	8092-002-US	9669

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EXAMINER	
THOMAS, DAVID C	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,429	ROMMENS ET AL.	
	Examiner	Art Unit	
	David C. Thomas	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,21 and 23-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,21 and 23-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, 21 and 53, drawn to a method for determining whether a subject is suffering from Shwachman-Diamond Syndrome (SDS) or is an SDS carrier based on the presence or absence of a Shwachman-Bodian-Diamond Syndrome (SBDS) gene mutation associated with SDS.

Group II, claim(s) 23 and 24, drawn to a method for determining whether a subject is suffering from Shwachman-Diamond Syndrome (SDS) based on determining the level of SBDS protein in a tissue sample.

Group III, claim(s) 25, drawn to a method for determining whether a subject is at risk for developing acute myelogenous leukaemia (AML) based on the presence or absence of a SBDS gene mutation associated with SDS.

Group IV, claim(s) 26-30, drawn to a method for treating a subject suffering from SDS.

Group V, claim(s) 31-41, drawn to an isolated nucleic acid molecule encoding a SBDS protein, a fragment of said nucleic acid molecule, a recombinant vector comprising the isolated nucleic acid molecule and a host cell comprising the vector.

Group VI, claim(s) 42-46, drawn to a substantially purified SBDS protein, an antibody which binds to an epitope of the SBDS protein and a hybridoma cell line which produces the antibody.

Group VII, claim(s) 47, drawn to a method for preparing an SBDS protein.

Group VIII, claim(s) 48 and 52, drawn to a nucleotide sequence and a kit comprising at least one pair of primers.

Group IX, claim(s) 49-51, drawn to a transgenic non-human mammal having within its genome an SBDS gene with at least one mutation associated with SDS.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups V and VI, drawn to claims 31-41 and 42-46, respectively, included many claims which were found to be anticipated by the prior art, specifically, Helix Research Institute (EP 1 074 617A) (Accession Number AAH14710) and Isogai et al. (GenBank Accession Number AK001779), which are shown to be X references which anticipate many of the product claims drawn to a nucleic acid molecule encoding an SBDS protein. As MPEP 1893.03(d) notes "The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art." In the current case, the claims are drawn to a product in Groups V and VI, but these Groups do not make a contribution over the prior art because the invention is anticipated by the prior art. Therefore, there is no single inventive concept under PCT Rule 13.1 and the lack of unity requirement is proper.

In addition, should the applicant elect Group I, the applicant is required to select no more than one among the species of mutations: 24C>A; 97_97insA; 119delG; 131A>G; 183TA>CT; 183TA>CT + 201A>G+258+2T>C; 199A>G; 258+2T>C; 258+1G>C; 260T>G; 291_293delTAAinsAGTI'CAAGTATC; 377G>C; 505C>T+651C>T, 183 184TA CT; 183 184TA CT+258+2T C; 258+2T C; 24C A; 96-97insA; 119delG;

131A G; 199A G; 258+1G C; 260T G; 291- 293delTAAinsAGTTCAAGTATC; 377G C; 505C T; 56G A; 93C G; 97A G; 101A T; 123delC; 279_284delTCAACT; 296_299delAAGA; 354A C; 428C T+443A G; 458A G; 460-1G A; 506G C; and 624+1G C. In addition, should the applicant elect Group V, the applicant is required to select no more than one among the species of human and murine nucleic acids encoding a SBDS protein.

The species listed in Groups I and V do not relate to a single general inventive concept under PCR Rule 13.1 because, under PCR Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The species of Group I are drawn to mutations at different sites within the SBDS gene, while the species of Group V are drawn to nucleotide sequences of different organisms.

In addition, should the applicant elect Group I or Group VIII, the applicant is required to select no more than one pair of primer sequences from Group X below. Should the applicant elect Group IV or Group V, the applicant is required to select no more than one sequence from Group XI below. Should the applicant elect Group VI, the applicant is required to select no more than one sequence from Group XII below:

Groups X, the individual SEQ ID Nos. 3-28 and 31-34, representing primer sequences generic to claims 7 and 48;

Groups XI, the individual SEQ ID Nos. 1, 2 and 29 representing nucleotide or amino acid sequences generic to claims 28-30, 33, 35 and 41.

Groups XII, the individual SEQ ID Nos. 2 and 29, representing amino acid sequences generic to claims 43 and 45.

The inventions listed in Groups X-XII do not relate to a single general inventive concept under PCR Rule 13.1 because, under PCR Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups X are drawn to unique primer sequences while Groups XI and XII are drawn to nucleotide or amino acid sequences, with each primer pair specific for amplifying a unique SBDS gene sequence, and the amino acid sequence, while encoded by the nucleotide sequence, represents a distinct molecular entity from the nucleotide sequence.

3. Applicant is also requested to amend the claims and/or the Sequence Listing so that the elected sequence is designated with a SEQ ID. NO. corresponding to the same sequence in the Sequence Listing. For example, SEQ ID NO. 3 in the claims is actually an amino acid sequence in the Sequence Listing. Claim 35 as well as the Specification cites both an amino acid sequence and nucleotide sequence of SEQ ID NO. 29. Finally, the Sequence Listing appears to be incomplete, as the final listing is for SEQ ID NO. 12. An updated Sequence Listing that matches the SEQ ID NOS. of the claims is required to render a meaningful search of the claims.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

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Assistant Examiner
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12/19/07

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